

Notice of Allowability

Application No.

10/669,301

Examiner

Golam M. M. Shameem, Ph.D.

Applicant(s)

VAYSSE-LUDOT ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 09/24/2003.
2. ☒ The allowed claim(s) is/are 16 and 19-30 (now 1-13).
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Election/Restrictions

- I. Claims 16 and 19-30 drawn to a process classified in class 549 and several subclasses.
- II. Claims 17 and 18 drawn to another process classified in class 549 and several subclasses.

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Group listed above are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lahu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art

reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

The above groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

Invention groups I-II, are related as different processes of making a product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product can be made by another materially different process (MPEP 806.05(f)). In the instant case, the process as claimed could be used to make at least one materially different product as demonstrated throughout the specification and Invention group II, which is directed to a different process / method for preparing for a different product.

Inventions are independent if it can be shown that they are not disclosed as capable of use together, having different modes of operation, different functions or different effects (MPEP 806.04, MPEP 808.01). In the instant case, different inventions are drawn to a single application (compounds, and their process of purification), requiring different search strategies and to search all the above groups in a single application would be an undue burden on the Examiner. Therefore a separate search considerations are involved, which would impose a burden if unrestricted. Also the fields of search are not coextensive. Additionally, besides performing a class/subclass search, the Examiner performs a commercial data base search and an automated patent system (text) search. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (subclasses), restriction for examination purpose as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purpose as indicated is proper.

A telephone call was made to Mr. Patrick Sage on 9/29/2005 to request an oral election to the above restriction requirement, and a provisional election was made without traverse to prosecute the invention of group I.

Advisory of Rejoinder

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims, which depend from or otherwise include all the limitations of the patentable product, will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejections are governed by 37 CFR 1.116. Process claims, which do not depend from or otherwise include the limitations of the patentable product, will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance is governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is

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paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims, which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brower* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of an allowed product claim**. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (Emphasis added)

Therefore, in accordance with M.P.EP 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.



Applicants preserve their right to file a divisional on the non-elected subject matter.

Priority

This application claims benefit for foreign priority under 35 U.S.C. § 119(a)-(d) to France 02.11763 09/24/2002 is acknowledged.

Status of Claims

Claims 16-30 are currently pending in the application. Claims 1-15 were canceled through preliminary amendment.

Claims 17 and 18 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, [which includes claims 16 and 19-30 drawn to a process for synthesis of the compound of formula (I)] **without** traverse is acknowledged. However, during a telephonic interview, with Mr. Patrick Sage (Attorney for Applicant) on September 29, 2005, Applicant has agreed to cancel non-elected claims 17 and 18 of Group II. Therefore, the restriction requirement is hereby withdrawn and hence, all remaining pending claims 16 and 19-30 have been examined and found allowable over the prior art.

Examiner's amendment

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Ms. Patrick Sage (Attorney for Applicant) on September 29, 2005.

The application has been amended as follows:

- a. Claims 17 and 18 have been canceled.
- b. In claim 16 (new), line 1, please delete the expression "The" after the word "industrial".
- c. In claim 16 (new), line 16, page 2, please delete the expression "aN" and insert with --an--.
- d. In claim 19 (new), line 2, please delete the expression "The" before the word "synthesis".
- e. In claim 22 (new), line 2, please delete the expression "The" before the word "synthesis".

Reasons for allowance

The following is an Examiner's statement of reasons for allowance:

Wierzbickii *et al* (EP 0415 850) teach the process of preparation of strontium ranelate derivatives and their method of uses thereof. The instant invention teaches a multi-step process of synthesis of the compound of formula (I) in the presence of morpholine to obtain the desired final product. The prior art process neither teaches nor renders obvious the instantly claimed invention and there is no suggestion or motivation to modify the process of other prior art to obtain the instant invention. Therefore, the instant claims 16 and 19-30 are allowable over the prior art of record.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 7:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph

McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (571) 273-8300. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.


Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

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GOLAM M. M. SHAMEEM, PH.D
PRIMARY EXAMINER

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October 11, 2005